

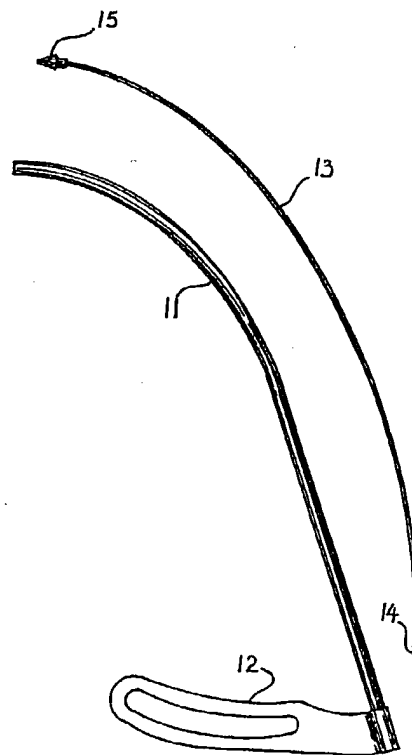


## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification 4 :</b>  <b>A61B 17/42, 17/06, 17/04</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 90/03766</b>  <b>(43) International Publication Date:</b> 19 April 1990 (19.04.90)
<b>(21) International Application Number:</b> PCT/AU89/00432 <b>(22) International Filing Date:</b> 4 October 1989 (04.10.89) <b>(30) Priority data:</b> PJ 0756 4 October 1988 (04.10.88) AU <b>(71)(72) Applicant and Inventor:</b> PETROS, Peter, Emanuel [AU/AU]; 3 Wilson Street, Claremont, W.A. 6010 (AU). <b>(74) Agents:</b> HARWOOD, Errol, John et al.; Wray & Associates, P.O. Box 6292, East Perth, W.A. 6004 (AU). <b>(81) Designated States:</b> AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CM (OAPI patent), DE, DE (European patent), DK, FI, FR (European patent), GA (OAPI patent), GB, GB (European patent),		HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC, MG, ML (OAPI patent), MR (OAPI patent), MW, NL, NL (European patent), NO, RO, SD, SE, SE (European patent), SN (OAPI patent), SU, TD (OAPI patent), TG (OAPI patent), US.  <b>Published</b> <i>With international search report.</i>

**(54) Title:** SURGICAL INSTRUMENT PROSTHESIS AND METHOD OF UTILISATION OF SUCH**(57) Abstract**

A method of treating female incontinence comprising looping a filamentary element (19) between the wall of the vagina (16) and the rectus abdominis sheath in the anterior wall of the abdomen whereby it passes to each side of the urethra (20) into the correct spatial relationship to the pubis (17), allowing the development of scar tissue between the vaginal wall (16) and the rectus abdominis sheath and removing the filamentary element (19). A surgical instrument for use with the method comprises a surgical instrument for the application of a filamentary element (19) into the body for the purpose of treating female incontinence said instrument comprising a tubular shaft (11) having a handle (12) at one end and carried toward its other end a flexible needle element (13) slidably receivable in the shaft (11) and adapted at one end to receive a filamentary element (19) and having an enlarged profiled portion (15) at its other end whereby when the needle element (13) is received in the shaft (11) the other end of the needle element (13) defines a convergent surface of the other end of the shaft (11) and the one end of the needle element (13) is exposed at the one end of the shaft (11). A corrective tissue prosthesis for use with the method, comprising an elongate flexible filamentary element (19) to which tissue will not attach itself.



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"Surgical Instrument Prosthesis and Method of Utilisation of Such"

THIS INVENTION relates to a surgical instrument for use in the treating of female incontinence and to a method of treating such incontinence.

In one form the invention resides in an instrument for the application of a filamentary element to the body for the purpose of treating female incontinence comprising a tubular shaft having a handle at one end and curved at its other end to the approximate of the general profile of the pubis between the vagina and the anterior surface of the abdomen, a needle element slidably receivable in other end of the shaft and adapted at one end to receive a filamentary element and having an enlarged profiled portion at its other end whereby when the needle element is received in the shaft the other end of the needle element defines a convergent surface at the other end of the shaft and the one end of the needle element is exposed at the one end of the shaft.

In another form the invention resides in a method of treating female incontinence comprising looping a filamentary element between the wall of the vagina and the rectus abdominis sheath in the anterior wall of the abdomen whereby it passes to each side of the urethra, tightening the loop to bring the vaginal wall and the urethra into the correct spatial relationship to the pubis allowing the development of scar tissue between the vaginal wall and the anterior wall of the abdomen pubic symphysis and removing the filamentary element.

The invention will be more fully understood in the light of the particular embodiment of the invention described below. The description is made with reference to the accompanying drawings of which:-

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Fig. 1 is a schematic sagittal section illustrating the circumstance which the urethro vesical junction wall is in a state of prolapse;

Figs. 2, 3 and 4 are sagittal sections illustrating the stages entry of the embodiment into the body;

Fig. 5 is a side elevation of the embodiment;

Fig. 6 is a side elevation of the embodiment with the needle element removed;

Fig. 7 is an isometric view of an alternative form of the embodiment; and

Fig. 8 is an isometric view of the form of the embodiment of Fig. 7 with the needle removed.

The embodiment is directed to a surgical tool for the treatment of female incontinence whereby as a result of the deterioration of the tissue or ligaments interconnecting the pubis with the vaginal wall. Such a condition can level to a loss of control of emissions from the urethra. The embodiment relates to an apparatus whereby the vaginal wall and urethra can be brought into a proper spatial relation with the pubis in order to restore continence. The embodiment comprises a surgical tool two forms of which are shown at Figs. 5 and 6 and 7 and 8 which comprise a tubular shaft 11 having a handle 12 at one end and curved at its other end to a configuration approximately corresponding to the general curvature of the pubis between the vaginal wall and the anterior surface of the abdomen. As shown at Figs. 7 and 8 which are directed to an alternative form of the invention the handle 12 may comprise a central radial arm 12a which is in the plane of curvature of the shaft to provide a positioning guide. The handle further comprises a pair of opposed arms 12b equally angularly offset from the central radial arm 12a. The opposed arms 12b provide facility for applying some leverage which may be required in using the instrument. The tubular shaft accommodates a needle

element 13 which is provided at one end with an eye 14 for receipt of a filamentary element (not shown). The other end of the needle element is formed with an enlarged conically shaped head portion 15 which is receivable at the other end of the shaft 11 to close the other end of the shaft and define a convergent substantially conical surface to facilitate penetration of the instrument through the body cavity.

In using the instrument and as shown at Figs. 2, 3 and 4 an incision is made in the vaginal wall 16 in the region of the urethro vesical junction. The other end of the instrument, having the needle element 13 therein, is passed through the incision made in the vaginal wall 16 and is passed through the body cavity around the pubis 17 until it contacts the muscle tissue 18 at the anterior wall of the abdomen. An incision is then made into the body wall at the point of contact of the other end of the instrument to allow passage of the instrument through the muscle tissue. A filamentary element 19 which takes the form of a tape is then applied through the eye of the needle element 13 and the needle element is withdrawn from the shaft such that the filamentary element 19 is pulled through the shaft. With the filamentary element 19 in place the shaft is then removed from the body while the filamentary element is stationary. A second incision is made into the vaginal wall 16 to the other side of the urethra 20. The surgical instrument having the needle element in place in the shaft is then inserted into the second incision and again the shaft 11 is passed through the body cavity until it contacts the muscle tissue 18 at the interior wall of the abdomen at a position spaced from the first incision in the muscle wall at which time a second incision is made in the anterior wall of the abdomen through which the other end of the surgical instrument is passed. The needle element is then removed

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from the shaft while the shaft is held in position and the end of the filamentary element which is in place in the body is then engaged through the eye of the needle element. The needle is then reinserted into the shaft such that the filamentary element 19 is carried to the one end of the shaft where it is disconnected from the needle element 13. The needle element is then removed from the shaft 11. The shaft is then removed from the body while the filamentary element remains stationary. As a result the filamentary element is then looped around the muscle tissue 18 of the abdomen to either side of the urethra 20 with the ends extending into the vagina.

The filamentary element is left in place for a sufficient period of time for a scar tissue to develop around the filamentary element which provides a ligament like interconnection between the vaginal wall and the muscle tissue at the anterior surface of the abdomen. After satisfactory development of such tissue the ends of the filamentary element are disconnected and the filamentary element is removed from the body per vaginam.

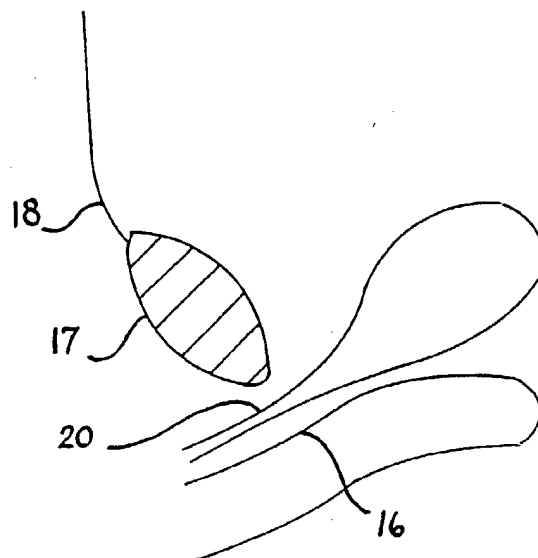
THE CLAIMS defining the invention are as follows:-

1. A surgical instrument for the application of a filamentary element into the body for the purpose of treating female incontinence said instrument comprising a tubular shaft having a handle at one end and carried toward its other end a flexible needle element slidably receivable in the shaft and adopted at one end to receive a filamentary element and having an enlarged profiled portion at its other end whereby when the needle element is received in the shaft the other end of the needle element defines a convergent surface of the other end of the shaft and the one end of the needle element is exposed at the one end of the shaft.
2. A surgical instrument as claimed at claim 1 wherein the curvature of the shaft approximates the general profile of the pubis between the vagina and the anterior surface of the abdomen.
3. A surgical instrument substantially as herein described.
4. A corrective tissue prosthesis comprising a flexible elongate element of a filamentary nature to which tissue will not attach itself.
5. A corrective tissue prosthesis substantially as herein described.
6. A method of treating female incontinence comprising looping a filamentary element between the wall of the vagina and the rectus abdominis sheath in the anterior wall of the abdomen whereby it passes to each side of the urethra into the correct spatial relationship to the

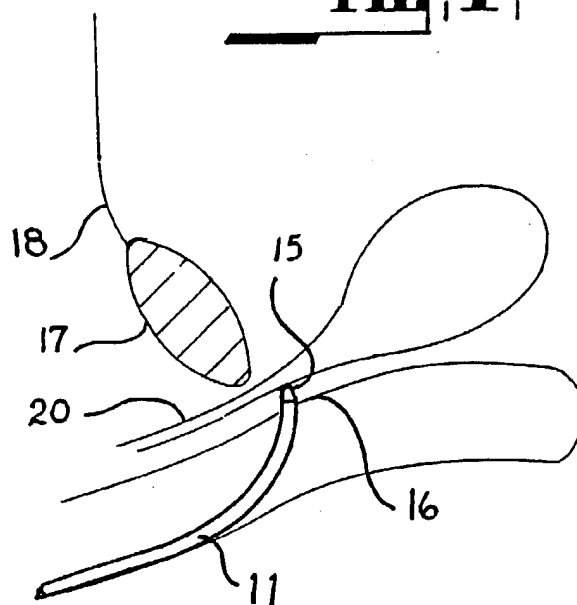
pubis, allowing the development of scar tissue between the vaginal wall and the rectus abdominis sheath and removing the filamentary element.

7. A method substantially as herein described.

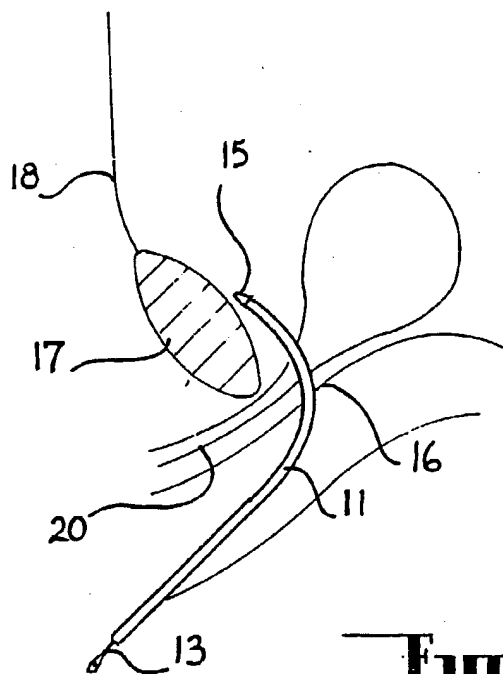




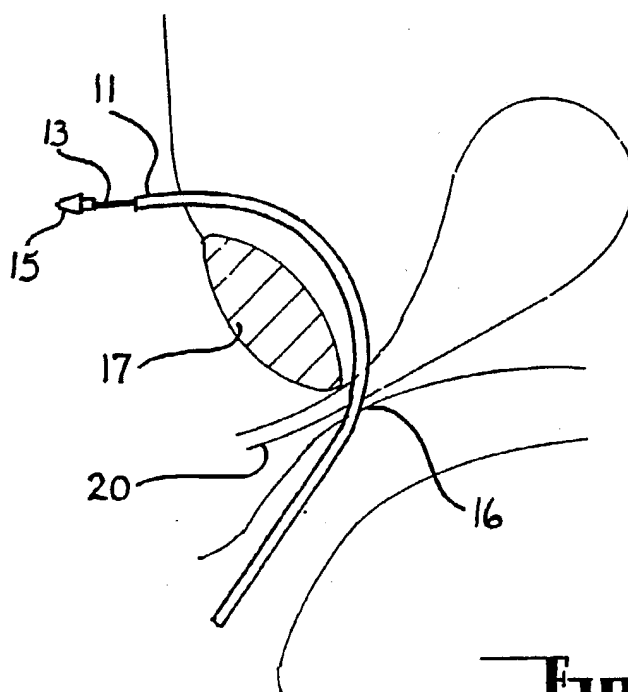
**Fig. 1**



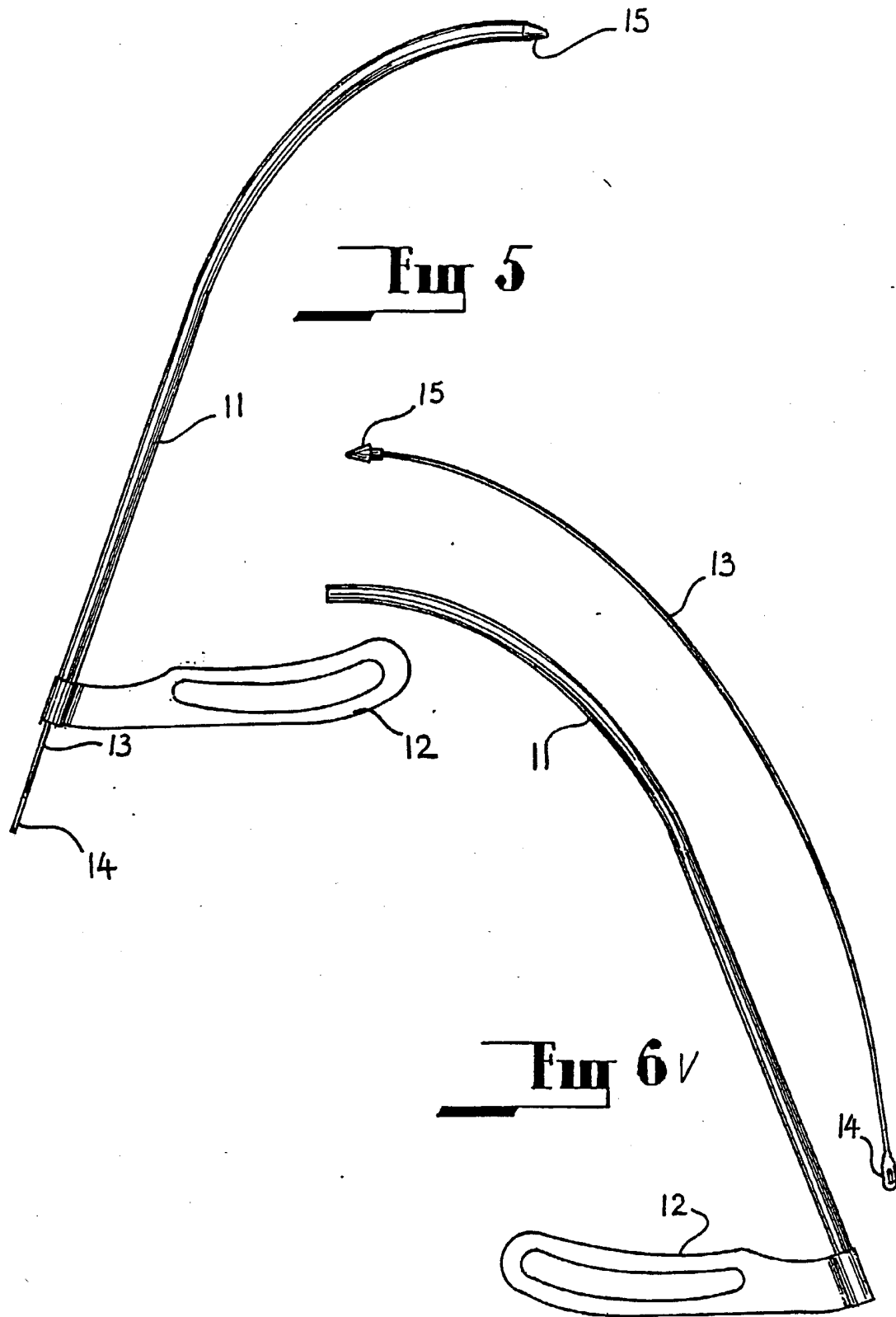
**Fig. 2**

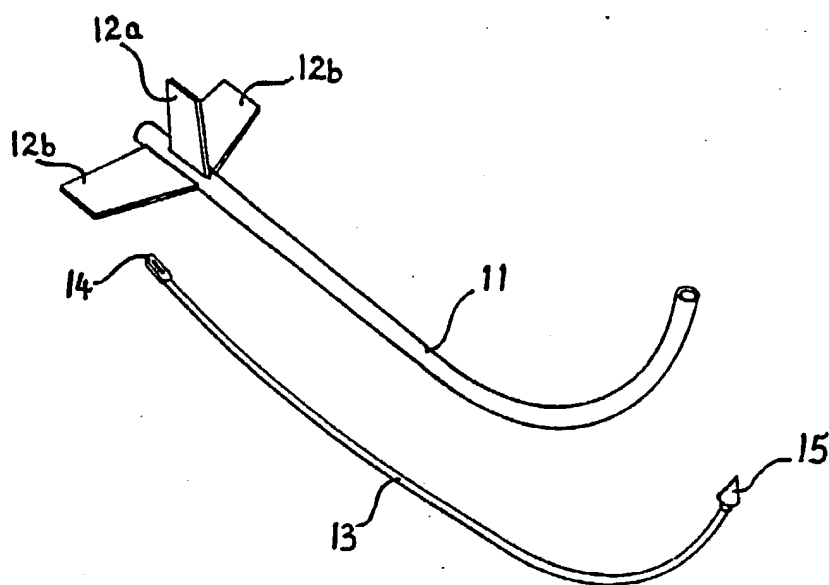
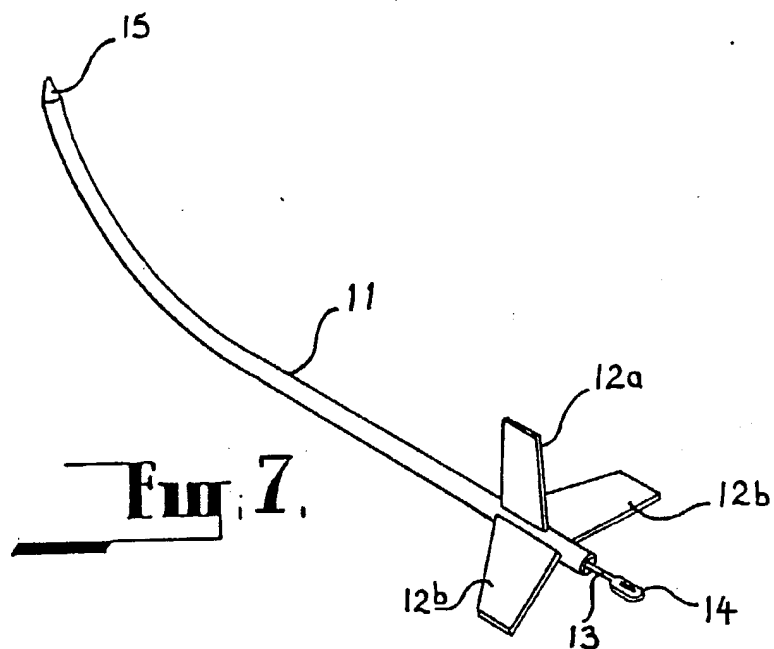


**Fig. 3,**



**Fig. 4,**





# INTERNATIONAL SEARCH REPORT

International Application No. PCT/AU 89/00432

<b>I. CLASSIFICATION OF SUBJECT MATTER</b> (if several classification symbols apply, indicate all) 6		
According to International Patent Classification (IPC) or to both National Classification and IPC		
Int. Cl. <sup>4</sup> A61B 17/42, 17/06, 17/04		
<b>II. FIELDS SEARCHED</b>		
Minimum Documentation Searched 7		
Classification System	Classification Symbols	
IPC	A61B 17/42, 17/06, 17/04 A61F 2/02, 2/04 A61L 17/00	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 8		
<b>III. DOCUMENTS CONSIDERED TO BE RELEVANT</b> 9		
Category*	Citation of Document, <sup>11</sup> with indication, where appropriate, of the relevant passages 12	Relevant to Claim No 13
X	US-A-4235238 (OGIJI et al)	4
Y	25 November 1980 (25.11.80)	1-2
Y	US-A-4128100 (WENDORFF) 5 December 1978 (05.12.78)	1-2
X		4
X	US-A-3472232 (EARL)	4
Y	14 October 1969 (14.10.69)	1-2
Y	US-A-3311110 (SINGERMAN et al)	1-2
X	28 March 1967 (28.03.67)	4
X	US-A-4392495 (BAYERS)	4
Y	12 July 1983 (12.07.83)	1-2
<p>* Special categories of cited documents: 10</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</p> <p>"Z" document member of the same patent family</p>		
<b>IV. CERTIFICATION</b>		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
21 December 1989 (21.12.89)	January 1990	
International Searching Authority	Signature of Authorized Officer	
Australian Patent Office	A.W. DUKE	

## III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category*	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
X	US-A-3858783 (KAPITANOV et al)	4
Y	7 January 1975 (07.01.75)	1-2
Y	US-A-3763860 (CLARKE)	1-2
X	9 October 1973 (09.10.73)	4

## FURTHER INFORMATION CONTINUED FROM THE SECOND SHEET

Y	US-A-4037603 (WENDORFF)	1-2
X	26 July 1977 (26.07.77)	4
X,Y	AJ-B-441561 (16926/70) (ETHICON INC.) 6 January 1972 (06.01.72)	4
Y	AJ-B-278089 (38343/63) (ETHICON, INC) 3 June 1965 (03.06.65)	4
X	US-A-4441497 (PAUDLER)	4
Y	10 April 1984 (10.04.84)	1-2
Y	US-A-3924633 (COOK et al)	1-2
X	9 December 1975 (09.12.75)	4

V. ☐ OBSERVATIONS WHERE CERTAIN CLAIMS WERE FOUND UNSEARCHABLE 1

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim numbers, because they relate to subject matter not required to be searched by this Authority, namely:
  
2. ☐ Claim numbers, because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
  
3. ☐ Claim numbers, because they are dependent claims and are not drafted in accordance with the second and third sentences of PCT Rule 6.4 (a):

VI. ☒ OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING 2

This International Searching Authority found multiple inventions in this international application as follows:

- Claims 1-3 are directed to "A surgical instrument,"
- Claims 4 and 5 are directed to "A corrective tissue prosthesis,"
- Claims 6 and 7 are directed to "A method of treating female incontinence."

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims of the international application.
2. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims of the international application for which fees were paid, specifically claims:
  
3. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim numbers:
  
4. ☒ As all searchable claims could be searched without effort justifying an additional fee, the International Searching Authority did not invite payment of any additional fee.

## Remark on Protest

- ☐ The additional search fees were accompanied by applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON  
INTERNATIONAL APPLICATION NO. PCT/AU 89/00432

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Members		
US	4235238	DE	2919009	JP 54154282 JP 55005532
AU	441561	CA	968244	DE 2037813 FR 2055680
		GB	1305420	NL 7011148 US 3630205
		ZA	7005280	

END OF ANNEX